

03/01/04 16:57 FAX 2155685789

DB&R PHILA.

001



DRINKER BIDDLE & REATH LLP  
ONE LOGAN SQUARE  
18<sup>TH</sup> and Cherry Streets  
PHILADELPHIA, PA  
USA 19103-6996

Telephone: (215) 988-2700  
FACSIMILE NUMBER: (215) 988-2757

**DATE:** March 1, 2004

**FAX NO.:** 703) 305-3230

**TO:** **ATTN: INDIA L. EVANS**

**FROM:** Karen M. Spina --Legal Assistant for  
Daniel A. Monaco, Esq. -- Tel.: (215) 988-3312 (Reg. No. 30,480)  
Customer No. 23973

**RE:** **US Application No. 09/831,686**  
**Attorney Docket: 37921-151956 (43232-1)**

**PAGES:** 34

**COMMENTS:** Dear India -- As we discussed today, please find attached in connection with the above-identified application:  
Copies of (1) FORM PCT/DO/EO/918 mailed 02/23/04;  
(2) Notification of Defective Response; (3) complete Response to Formalities Letter as mailed to the USPTO on February 18, 2004;  
(4) Express Mail Label No. EL998872976US; and (5) postcard receipt (date-stamped postcard not yet received in our offices).

**THANK YOU FOR YOUR ASSISTANCE**

**ORIGINAL:**

The information contained in this facsimile message is attorney privileged and confidential information intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address by mail. Thank you.

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PHIP\361994\1



## UNITED STATES PATENT AND TRADEMARK OFFICE

167321

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/831,686	Stephen Alister Locarnini	37921151956
23973 DRINKER BIDDLE & REATH ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996		INTERNATIONAL APPLICATION NO.
		PCT/AU99/00993
FEB 27 2004		1A. FILING DATE PRIORITY DATE
		11/10/1999 11/11/1998
CONFIRMATION NO. 7052		
371 FORMALITIES LETTER		
 *OC000000011952929		

Date Mailed: 02/23/2004

## NOTIFICATION OF DEFECTIVE RESPONSE ABANDONMENT

The United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495) has made the following determination:

Applicant has failed to properly respond to the notification of MISSING REQUIREMENTS (Form PCT/DO/EO/905), mailed 06/13/2001 within the time period set therein.

Therefore, the above identified application failed to meet the requirements of 35 U.S.C. 371 and 37 CFR 1.495, and is ABANDONED AS TO THE UNITED STATES OF AMERICA.

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5).

*A copy of this notice MUST be returned with the response.*

INDIA L EVANS

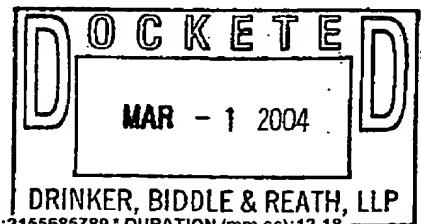
Telephone: (703) 305-2936

## PART 2 - OFFICE COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
09/831,686	PCT/AU99/00993	37921151956

FORM PCT/DO/EO/918 (371 Formalities Notice)

COPY





**UNITED STATES PATENT AND TRADEMARK OFFICE**

UNITED STATES DEPARTMENT OF COMMERCE  
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Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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INTERNATIONAL APPLICATION NO.		
PCT/AU99/00993		
I.A. FILING DATE		PRIORITY DATE
11/10/1999		11/11/1998
CONFIRMATION NO. 7052		
371 FORMALITIES LETTER		
 *OC000000010828228*		

Date Mailed: 09/08/2003

**NOTIFICATION OF DEFECTIVE RESPONSE**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Indication of Small Entity Status
- Priority Document
- Original Specification filed on 07/31/2001
- Drawings filed on 07/31/2001
- Claims filed on 07/31/2001
- Oath or Declaration filed on 07/31/2001
- Initial Application Filing Fees filed on 07/31/2001
- Small Entity Statement filed on 07/31/2001
- Copy of the International Application filed on 05/10/2001
- Copy of the International Search Report filed on 05/10/2001
- Copy of IPE Report filed on 05/10/2001
- Preliminary Amendments filed on 05/10/2001
- Information Disclosure Statements filed on 04/23/2002
- Biochemical Sequence Diskette filed on 07/31/2001
- Oath or Declaration filed on 07/31/2001
- Biochemical Sequence Listing filed on 07/31/2001
- Request for Immediate Examination filed on 05/10/2001
- U.S. Basic National Fees filed on 05/10/2001
- Power of Attorney filed on 07/31/2001

**COPY**

Applicant's response filed 04/23/2002 is hereby acknowledged. The following requirements set forth in the NOTIFICATION OF MISSING REQUIREMENTS mailed 06/13/2001 have not been completed.

**Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).**

The following items **MUST** be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):
  - The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
  - **APPLICANT MUST PROVIDE:**
    - An initial or substitute computer readable form (CRF) of the "Sequence Listing."
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
  - For Rules Interpretation, call (703) 308-4216
  - To Purchase PatentIn Software, call (703) 306-2600
  - For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

INDIA L EVANS

Telephone: (703) 305-2936

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
09/831,686	PCT/AU99/00993	37921151956

FORM PCT/DO/EO/916 (371 Formalities Notice)

COPY

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COPY

Attorney Docket No. 43232-1  
Re: Patent Application of LOCARNINI et al.  
Appl. No.: 09/631,688  
Appl. No.: 09/631,688 filed November 10, 1999  
1A. PCT/AU98/00993 filed November 10, 1999  
1A. BIOLOGICAL COMPOSITIONS, COMPONENTS THEREOF  
For: USES THEREFOR  
The U.S. Patent Office acknowledges and has stamped hereon the date of receipt of  
the attached paper(s):  
the attached paper(s):  
(1) PTO/SB/64/PCT (substituted) PETITION FOR REVIVAL OF AN INTERNATIONAL  
APPLICATION FOR PATENT DESIGNATING THE U.S. ABANDONED  
UNINTENTIONALLY UNDER 37 CFR 1.137(B)  
(2) Response to 37/1 NOTIFICATION OF DEFECTIVE RESPONSE  
(3) Sequence Listing Diskette; (4) Paper Copy of Sequence Listing  
(5) Check for Petition fee \$850

Certificate of Express Mailing 1.10: February 18, 2004  
Express Mail Label No.: **EL 998872976 US**  
(37921-151956)



COPY

PTO/SB/64/PCT (06-03)

Approved for use 12/31/2003. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**PETITION FOR REVIVAL OF AN INTERNATIONAL APPLICATION FOR PATENT  
DESIGNATING THE U.S. ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)**

Docket Number  
(Optional)  
43232-1

First Named Inventor: Stephen Alister LOCARNINI et al.

International (PCT) Application No.: PCT/AU99/00993

U.S. Application No.: 09/831,686  
(if known)

Filed: November 10, 1999

Title: BIOLOGICAL COMPOSITIONS, COMPONENTS THEREOF AND USES THEREFOR

Attention: PCT Legal Staff  
Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

The above-identified application became abandoned as to the United States for failure to reply to the NOTIFICATION OF DEFECTIVE RESPONSE mailed on September 8, 2003. The date of abandonment is October 9, 2003 (the day after the date on which the response to the Notification was due).

**APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION**

NOTE: A grantable petition requires the following items:

- (1) Petition fee
- (2) Proper reply
- (3) Terminal disclaimer with disclaimer fee which is required for all international applications having an international filing date before June 8, 1995; and
- (4) Statement that the entire delay was unintentional.

**1. Petition fee**

Small entity - fee \$ 650 (37 CFR 1.17(m)). Applicant claims small entity status.  
See 37 CFR 1.27.

Other than small entity - fee \$ (37 CFR 1.17(m))

**2. Proper reply**

A. The proper reply (the missing 35 U.S.C. 371(c) requirement(s)) in the form of response to  
Notification of Defective Response (Identify type of reply):  
include Substitute Computer-Readable Form of Sequence Listing (37 CFR 1.825 (d))

has been filed previously on \_\_\_\_\_

Is enclosed herewith.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.137(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-8199 and select option 2.

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PTO/SB/64/PCT (08-03)

Approved for use through 12/31/2003. OMB 0651-0221

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

## 3. Terminal disclaimer with disclaimer fee

Since this international application has an international filing date on or after June 8, 1995, no terminal disclaimer is required.

A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of \$ \_\_\_\_\_ for a small entity or \$ \_\_\_\_\_ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

## 4. Statement. The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

February 18, 2004

Date

(215) 988-3312

Telephone Number

30,480

Registration Number, if applicable

Signature

DANIEL A. MONACO

Typed or Printed Name

DRINKER BIDDLE & REATH LLP  
 One Logan Square, 18th and Cherry Streets  
 Philadelphia, PA 19103-6996

Address

Address

Enclosures:  Response to Notification of Defective Response, including substitute computer readable format of sequence listing and paper copy  
 Fee Payment  
 Terminal Disclaimer  
 Postcard receipt

COPY PATENT

Atty. Docket No.: 43232-1

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent application of  
Stephen Alister LOCARNINI *et al.*

International Application No.  
PCT/AU99/00993

Int'l Filing Date:  
November 10, 1999

For: BIOLOGICAL COMPOSITIONS,  
COMPONENTS THEREOF AND USES  
THEREFOR

ATTN: PCT Legal Staff  
Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

U.S. Application No.  
09/831,686

Confirmation No. 7052

Response to Notice of Defective Response

Sir:

Submitted herewith is a response to the NOTIFICATION OF DEFECTIVE RESPONSE mailed on September 8, 2003. A copy of the Notification is submitted herewith. This response is being submitted with a PETITION FOR REVIVAL OF AN INTERNATIONAL APPLICATION FOR PATENT DESIGNATING THE U.S. ABANDONED UNINTENTIONALLY UNDER 37 C.F.R. § 1.137(b).

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10	
EXPRESS MAIL Mailing Label Number: Date of Deposit:	EL 908872976 US February 17, 2004
I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, on the date indicated above, and addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
Signature of person mailing page: <u>Karen M. Spina</u> Type or print name of person	

U.S. Application No. 09/831,686

Attorney Docket No. 43232-1

REMARKS

Please note the change in attorney docket number (it is now 43232-1).

The Notification of Defective Response indicated that the computer readable form of the sequence listing submitted on April 23, 2002 contained errors, which were detailed in the attached CRF Diskette Problem Report. The Applicants enclose a substitute computer readable form of the sequence listing, in which these errors have been corrected.

A substitute paper copy of the sequence listing, which is identical to the computer readable form of the sequence listing, is also provided. Please amend the present application by replacing the existing paper copy of the sequence listing with the paper copy of the sequence listing submitted herewith.

The errors identified in the CRF Diskette Problem Report were corrected as follows. No new matter was introduced by these corrections.

Field <213> for SEQ ID NOS: 1-4 was changed to read "Artificial sequence," per 37 C.F.R. 1.823, and field <223> for SEQ ID NOS: 1-4 was changed to indicate that the sequences are synthetic.

The feature description for amino acid 25 in SEQ ID NO: 1 previously identified amino acid 25 as "Xaa = L or R." However, both SEQ ID NO: 1 and Formula I on pgs. 8-11 of the specification (which corresponds to SEQ ID NO: 1) indicate that amino acid 25 in SEQ ID NO: 1 is an isoleucine. The feature description for amino acid 26 of SEQ ID NO: 1 incorrectly indicated that "Xaa = T or K," and failed to include a feature description for amino acid 27 (which is also an "Xaa"). Formula I shows that amino acid 26 of SEQ ID NO: 1 is leucine (L) or arginine (R), and that amino acid 27 of SEQ ID NO: 1 is threonine (T) or lysine (K). The feature descriptions were therefore changed to indicate that amino acid 26 is "Xaa = L or R," and that amino acid 27 is "Xaa = T or K," and to delete the feature description for amino acid 25. No new matter has been introduced by these changes.

The feature description for amino acid 2 in SEQ ID NO: 2 indicated that "Xaa = N or D." As pointed out by the Examiner, an amino acid which can be either asparagine (N) or aspartic acid (D) should be indicated by "Asx" in the actual sequence. SEQ ID NO: 2 has therefore been amended to replace the "Xaa" at position 2 with "Asx," and the feature description for this amino acid has been eliminated as unnecessary. No new matter has been introduced by this change.

U.S. Application N

09/831,686

orney Docket No. 43232-1

"Glx" instead of "Xaa" was also inadvertently used SEQ ID NO: 2 to indicate variant amino acids, except for amino acid 141 (which can be either glutamine or glutamic acid) and was thus correctly identified as "Glx". The feature descriptions for SEQ ID NO: 2, as well as Formula II on pgs. 14-17 of the specification (which corresponds to SEQ ID NO: 2), show that none of the variant amino acids except amino acid 141 are Glx. All occurrences of "Glx" in SEQ ID NO: 2, except for amino acid 141, were therefore changed to "Xaa." No new matter has been introduced by these changes.

The feature descriptions of SEQ ID NO: 2 also used the symbol "Z" instead of "Xaa" in reference to the variant amino acids in the sequence. Each symbol "Z" in the feature descriptions of SEQ ID NO: 2 was therefore replaced with "Xaa." No new matter has been added by these changes.

The feature description for amino acid 130 of SEQ ID NO: 2, which indicated that "M = amino acid 550," has been deleted.

Amino acid 150 of SEQ ID NO: 2 is "Xaa," but no feature description for this amino acid was included in the sequence listing. Formula II indicates that amino acid 150 in SEQ ID NO: 2 is either valine or isoleucine. A feature description for amino acid 150 which reads "Xaa = V or I" was therefore added. No new matter has been introduced by this change.

The feature descriptions for SEQ ID NO: 3, which is a synthetic DNA sequence, defined numerous variant nucleotides and indicated that each variant nucleotide could be one of two specific bases. (For example, the nucleotide at position 3 can be A or C.) The symbol "n" was used in SEQ ID NO: 3 to indicate the variant nucleotides. However, the one-letter codes set forth in the PCT Administrative Instructions, Annex C, Appendix 2, Table 1 should be used for variant nucleotides which can be one of two different, but defined, bases. 37 C.F.R. 1.822(b). SEQ ID NO: 3 has been amended to replace each "n" in the sequence with the appropriate one-letter code, and the feature descriptions for this sequence have been deleted as unnecessary. No new matter has been added by these changes.

Field <221> in the feature descriptions for SEQ ID NO: 4 used the term "misc" to describe the features. The Examiner suggested using "misc\_feature" in this field; however, "misc\_feature" should only be used in reference to nucleic acid sequences, and SEQ ID NO: 4 is a protein. Therefore, each field <221> in the feature descriptions for SEQ ID NO: 4 was changed from "misc" to "variant." No new matter has been added by these changes.

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The originally-filed SEQ ID NO: 4 had incorrectly listed the variant amino acids by placing each alternative amino acid into the sequence itself, rather than indicating each variant by "Xaa" and defining the variants in the feature descriptions. Also, many of the arginines in the sequence were inadvertently listed as "Xaa," and defined as "X = N" in the feature descriptions (wherein "N" was meant to indicate arginine). Page 6, lns. 6-14 and page 30, lns. 14 of the present specification indicate that the consensus amino acid of SEQ ID NO: 4 is set forth in Fig. 2. See also the "Amendment and Statement under 37 C.F.R. 1.821(f)(g)" filed on April 9, 2003. To correct the errors appearing in SEQ ID NO: 4 as originally filed, SEQ ID NO: 4 has been replaced by a properly-formatted amino acid sequence corresponding to the consensus sequence of Fig. 2. No new matter has been added by this amendment.

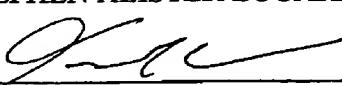
Finally, Field <213> for each of SEQ ID NOS: 5-16 used the term "HBV" to indicate that these sequences originated from hepatitis B virus. The term "HBV" in each field <213> for SEQ ID NOS: 5-16 has been replaced by the proper scientific name (genus and species), for hepatitis B virus; i.e., *Orthohepadnovirus hepatitis B*. No new matter has been added by these changes.

**Statement Under 37 C.F.R. 1.825(b)**

The undersigned hereby states that the substitute paper copy of the sequence listing submitted herewith is identical to the computer readable form of the sequence listing, which is also submitted herewith.

Respectfully submitted

STEPHEN ALISTER LOCARNINI *et al.*

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*Attorney for Applicants*

43232-1.TXT

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Joseph Torresi  
Linda Ernest-Silvera  
Angela Ingrid Bartholomeusz

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 Ser Ser Gly Leu Xaa Arg Tyr Val Ala Arg Leu Ser Ser Xaa Ser xaa  
 35 40 45  
 Asn Ile Xaa Asn Xaa Gln xaa Xaa Xaa Xaa Xaa Xaa Leu His Xaa Xaa  
 50 55 60  
 Cys Ser Arg Xaa Leu Tyr Val Ser Leu Xaa Leu Leu Tyr Xaa Thr xaa  
 65 70 75 80  
 Gly Xaa Lys Leu His Leu Xaa Xaa His Pro Ile Xaa Leu Gly Phe Arg  
 85 90 95  
 Lys Xaa Pro Met Gly Xaa Gly Leu Ser Pro Phe Leu Leu Ala Gln Phe  
 100 105 110  
 Thr Ser Ala Ile Xaa Xaa Xaa Xaa Xaa Arg Ala Phe Xaa His Cys Xaa  
 115 120 125  
 Xaa Phe Xaa Tyr Met Asp Asp Xaa Val Leu Gly Ala Xaa Xaa Xaa Xaa  
 130 135 140  
 His Xaa Glu Xaa Leu Xaa Xaa Xaa Xaa Xaa Xaa Leu Leu Xaa Xaa  
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## 43232-1.TXT

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&lt;210&gt; 8

&lt;211&gt; 426

&lt;212&gt; DNA

&lt;213&gt; Orthohepadnavirus hepatitis B

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&lt;210&gt; 9

&lt;211&gt; 426

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&lt;213&gt; Orthohepadnavirus hepatitis B

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&lt;213&gt; Orthohepadnavirus hepatitis B

43232-1.TXT

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&lt;212&gt; DNA

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&lt;213&gt; Orthohepadnavirus hepatitis B

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&lt;211&gt; 426

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&lt;213&gt; Orthohepadnavirus hepatitis B

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